

REMARKS

In this response, claims 63, 64, 66, 69-74, 76, 77, 94, 95, 100-108, 110 and 111 are canceled, claims 65, 67, 68, 79-82 and 96-99 are amended and claims 113-145 are added.

Applicants' claims recite a system for detecting the growth of microorganisms in a sample. Claim 79, the remaining independent claim from the claims previously presented, recites an apparatus with a module comprising a plurality of openings configured for receiving a plurality of containers. The system also comprises a laser that emits through at least one of said containers radiation at a substantially single wavelength at which a gas, selected from the group consisting of O₂ gas, NH₃ gas, H₂ gas, CH₄ gas, and CO₂ gas, absorbs radiation. Claim 79 specifies the substantially single wavelength at which CO₂ absorbs radiation as approximately 2.004 micrometers. The system further comprises a detector that detects at least a portion of the radiation that passes through said container and a signal analyzer that analyzes said detected radiation wherein the signal analyzer determines at least one parameter of the gas. As recited in claim 79, that parameter is either the pressure of the gas in the container, the existence of the gas in the container, or the concentration of the gas in the container.

In prior Office Actions, the Examiner has rejected all of applicants' pending claims in view of numerous references. Those rejections, as they pertain to the canceled claims enumerated above, are rendered moot by the cancellation of those claims and are not discussed herein. With regard to the amended claims (79 and the claims dependent therefrom), applicants submit the following reply.

Claim 79 as amended recites a system having a laser that emits, through at least one of the plurality of containers

recited in the claims, radiation at a substantially single wavelength. That substantially single wavelength is one at which one of the following gases absorbs radiation: O₂, NH₃, H₂S, CH₄, and CO₂. With regard to CO₂ gas, that wavelength is specified approximately 2.004 microns.

In the Office Action mailed August 9, 2006, with regard to claim 79, that claim along with claims 80, 82-84, 91 and 92 was rejected by the Examiner as obvious under 35 U.S.C. § 1023(a). The Examiner cited "Sussman et al." (U.S. 5,155,019) in view of "Wrobel et al." (U.S. 3,831,030), "Noller" (U.S. 4,857,735) or "Veale" (U.S. 6,639,678), taken further in view of "Nicks et al." (U.S. 5,473,161) as the basis for this rejection.

At the outset, applicants note that their previously submitted declaration under 35 U.S.C. 1.131 has been found by the Examiner to be deficient. The purpose of the 131 declaration was to remove the Veale reference from consideration.

Specifically, the Examiner objects to the declaration because, in the Examiner's view, the declaration was not commensurate in scope with the claims. The applicants submit that this deficiency has been addressed both by the supplemental declaration submitted herewith and the amendments to the claims. Specifically, in addition to the 2.004 micron wavelength (for CO₂ absorption) specified in claim 79, claim 79 is amended to identify the substantially single wavelength for target gases previously identified in canceled claim 63 (oxygen) and canceled claim 94 (NH₃, H₂S, CH₄, and SO₂). The supplemental declaration submitted herewith also expressly states that the laser used in the described reduction to practice emitted radiation at a substantially single wavelength of approximately 2.004 microns. Consequently, the declaration submitted herewith, when combined with applicants' previously declaration, is commensurate with

the scope of pending independent claim 79. Consequently, applicants submit that Veale has been removed as a reference against claim 79 and the claims depending therefrom.

Veale having been removed as a reference, applicants briefly address the Examiner's prior rejection in the context of amended claim 79.

As the applicants stated in their prior responses, Sussman et al. describes the use of an FT-IR technique to detect the presence of CO₂ in a container. In Sussman et al., the container has a sterile growth medium. When a sample is introduced into the container, the container is monitored for CO₂, which is a byproduct of metabolic processes in the container. The Sussman et al. reference teaches that the wavelengths of interest for CO₂ detection are in a range of 4.35 microns to 4.17 microns (col. 4, ln. 36). This corresponds to the transparency window for the polymethylpentene containers described in Sussman (4.26 microns) (col. 4, lns. 61-62). Applicants have repeatedly stressed the difference between the wavelengths identified in Sussman et al. for CO₂ detection and the substantially single CO₂ absorption wavelength of 2.004 microns recited in claim 79 of the present application. Applicants have previously stressed the advantages of using this wavelength to detect CO₂ absorption, as opposed to the wavelength disclosed in Sussman et al.

The Examiner has rejected applicants' arguments, which are based upon the difference in wavelength and the difference in laser sources that emit at the claimed substantially single wavelength(s). The Examiner argues that the teachings of Sussman et al. direct one skilled in the art to select the wavelength of radiation that corresponds to the absorption wavelength of the gas being detected. The Examiner ignores the many teachings in Sussman et al. that teach away from using a single wavelength emission source at the claimed wavelength for

detecting the presence of CO₂ in a container. More importantly, the Examiner ignores the many aspects of Sussman et al. that do not provide the requisite teaching, suggestion or motivation to one skilled in the art to combine Sussman et al. with the other references cited by the Examiner.

Specifically, applicants' invention, as recited in claim 79, is more than just a laser that emits radiation at a substantially single wavelength that is absorbed by a target gas. Applicants' invention is a system for detecting that target gas that employs the claimed laser. In addition to the laser, there is a detector configured to detect at least a portion of the radiation that passes through the container. There is a signal analyzer that analyzes the detected radiation. The signal analyzer determines at least one parameter of the gas selected from either the pressure of the gas in the container, the existence of the gas in the container or the concentration of the gas in the container.

With regard to the claimed system, Sussman et al. describes the use of an FT-IR technique to monitor the presence of CO₂ in a container. Applicants have previously noted that Sussman et al. does not teach the claimed wavelength for laser emission that is recited in claim 79. Nor does Sussman et al. describe the use of a laser source that emits at a substantially single wavelength. Col.4, ll. 36.

In conjunction with its use of a fairly broadband laser source (4.16 microns to 4.35 microns), Sussman et al. teaches the use of an FT-IR technique for monitoring the absorption of the radiation by the gas in the container. Applicants submit that the use of FT-IR spectroscopy in Sussman et al. actually teaches away from the claimed invention by teaching a spectroscopy technique that is not consistent with the use of the claimed substantially single wavelength laser source.

With regard to the claimed wavelength of 2.004 nm (for CO₂ detection) Sussman et al., at column 4, line 56 to column 5, line 6 discusses the relationship between the transparency of the plastic sample-containing vial at the transmission wavelength and the absorption spectrum of CO₂. Sussman et al. expressly teaches that the transmission wavelength range described therein (2400 cm⁻¹ to 2300 cm⁻¹ (which is equivalent to 4.16 microns to 4.35 microns)) is particularly advantageous. Sussman et al. postulates that the reason this particular transmission wavelength is advantageous is because it corresponds to the covalent triple bond of organic molecules (and that such triple bonds are not typically found in polymeric (e.g. polymethylpentene)) vial material contemplated by Sussman et al.) Therefore, Sussman et al. clearly teaches away from using other emission wavelengths to test for the presence of CO₂ in a container.

The Examiner makes much of the statements in Sussman et al. at column 6, lines 25-34 to support the combination of Sussman et al. with other references. There, Sussman et al. states that other metabolically formed gases may be detected. However, Sussman et al. neither identifies those gases nor does Sussman et al. identify the wavelengths (or the emission sources for the wavelengths) that would be used to detect those gases. Sussman et al. does not even go so far as to suggest or teach that other gases of interest would have an infrared absorption band. Although Sussman et al. suggests that the container material for detecting the gas of interest have an infrared transmittance of at least +/- 10 CM⁻¹ at the absorption wavelength of the gaseous product with at least about 1% transmission at the wavelength region of interest, Sussman et al. neither identifies specific materials nor wavelengths at which those materials have the specified infrared transmittance. Since any teaching, suggestion, or motivation from Sussman et al

must come from the reference as a whole, see, e.g. Hodosh v. Block Drug Co., Inc., 786 F.2d 1136 (Fed. Cir. 1986), applicants submit that, as a whole, Sussman et al. does not teach, suggest or motivate one skilled in the art to make the substitutions to the teachings of Sussman et al. that the Examiner makes in support of the rejections discussed herein.

Specifically, Wrobel et al., at column 3, line 7, teaches the use of a semiconductor diode laser at a wavelength of 4.28 microns for spectroscopic analysis used for gas, specifically CO₂, detection. This is consistent with the teaching of Sussman et al. and outside the scope of the present invention. While Wrobel et al. does describe the use of a semiconductor diode laser for detection and quantitative determination of gases and vapors, Wrobel et al. does not disclose or suggest the use of the laser and absorption spectroscopy to detect the presence and quantity of metabolically produced gases. As such, Wrobel et al. does not disclose or suggest specific wavelengths for the detection of the gases enumerated in claim 79 (with regard to CO₂, the wavelength identified in Wrobel et al. is not the claimed wavelength). Also, Wrobel et al. is completely silent on the need for a container that does not absorb radiation at the target wavelength. With regard to the detector, Wrobel et al. discloses a mercury cadmium telluride infrared detector system.

With regard Noller, it is difficult to understand how the Examiner can legitimately combine the teachings of Noller with the other references. Specifically, Noller discloses the use of a laser to detect components of liquid not gas, by spectrophotometry. The spectrophotometer is calibrated using a blank solution. The technique described in Noller is totally different from the technique described in Sussman et al. Moreover, Noller states that the target wavelength for the infrared radiation source is about 940 nanometers. This is

quite different from the wavelengths of interest identified by the applicants. Thus, one skilled in the art would not combine the teachings of Noller et al. with those of Sussman et al.

The Nix reference teaches away from applicants' invention by disclosing a source for radiation that is a broad IR beam. The radiation sources in Nix are specified to have wavenumbers in the range of 4922 to 5034. Nix et al. describes measuring the concentration of CO₂ gas in a sealed container. Importantly, Nix is directed to measuring the CO₂ concentration in the context of determining the shelf life of carbonated beverage bottles. According to Nix, the foundation of the technique rests upon taking measurements at the proper wavelengths within the red spectrum. Therefore, rather than using a laser source at a substantially single wavelength, Nix et al. employs a laser source that provides a range of wavelengths within the infrared spectrum. Nix et al. also contemplates the use of plastic bottles (PET). Column 6, line 66 to column 7, line 12. According to Nix et al., the choice of wavelengths in the range of 5034 to 4922 nanometers allows for the use of glass as well as PET containers. In this regard, Nix et al. notes that traditional mid-infrared techniques could not analyze the 4922 nanometer peak for a glass container. This directly contradicts Sussman et al., which teaches that glass is not a suitable container for gas detection using infrared spectroscopy. Based upon these contradictory teachings, it is difficult to understand how Nix et al. and Sussman et al. can be combined at all. Therefore, while Nix et al. may teach the wavelength claimed by applicants for CO₂ detection, Nix et al. cannot be combined with Sussman et al. in the manner in which the Examiner combined them because Sussman et al. teaches away from the wavelength specified by Nix et al. and Nix et al. teaches away from the wavelength specified by Sussman et al.

For these reasons, applicants submit that amended claim 79 and the claims dependent thereon are patentable over the asserted combination.

With regard to the dependent claims, applicants have previously addressed the specific rejections with regard to the dependent claims in prior responses. Applicants will again address these rejections. However, all of the previously presented dependent claims have either been canceled or amended to depend from claim 79. Applicants submit that dependent claims 65, 67, 68, 80-92 and 96-99 are patentable by virtue of the fact that they depend from claim 79.

With regard to claims 65 67 and 68, applicants submit that these claims are patentable over the above-discussed references and further in view of "Ahnell et al." (US 4,073,691) and "Wong" (US 4,730,112). With regard to Ahnell et al., the applicants again fail to understand what would motivate one skilled in the art to combine the teachings of the mass spectrometry measurement technique in this reference with Sussman et al. Granted Ahnell et al. states that CO₂ and other gases, such as O₂, are gaseous products of a biological process (Col. 4, ll. 46; Col. 7, ll. 35-45)). However, Ahnell et al. does not disclose or suggest aspects of applicants' claimed measurement technique for detecting the presence of O₂. Specifically, Ahnell et al. does not disclose or suggest that one might use a laser that emits radiation at a substantially single wavelength and to use absorption spectroscopy to determine whether O₂ is present in a sample container as evidence of biological activity within that container.

Wong describes the use of a laser that emits radiation spanning the 750 nm to 870 nm region. Thus, Wong teaches away from the present invention by using a laser that emits over a wide band as opposed to a substantially single wavelength. Wong teaches away from the present invention by indicating that the

weakness of the oxygen "A" system requires the use of a relatively broadband source. Col. 3, line 46.

Thus, for the foregoing reasons applicants submit that claims 65, 67 and 68 are patentable over the cited combination of references.

With regard to claims 80-84, applicants submit that these claims are patentable over the cited references for the same reason that claim 79 is patentable over those cited references.

With regard to claims 85-89, applicants submit that the structural features of these claims, in combination with claim 79, are not obvious in view of the cited references.

Claims 85-87 stand rejected over the combination of references used to reject claim 79 and further in view of "Carr et al." (US 5,888,825). The Examiner acknowledges that there is nothing in Carr et al. (which describes a housing for storing and examining culture vessels) that suggests using a laser spectroscopy technique for examining the culture vessels stored in Carr et al. The Examiner has not cited anything in Sussman et al. or the other references that suggest using the measurement techniques described in those references (e.g. laser spectroscopy, FT-IR, etc.) for samples in an apparatus like the one described in Carr et al. For these reasons, applicants submit that claims 85-87 are patentable over the cited combination of references.

Claims 88-89 stand rejected over the combination of references used to reject claim 79 and further in view of "Berndt et al." (US 5,888,825). The Examiner acknowledges that there is nothing in Berndt et al. (which describes using a fluorescence sensor for detecting biological activity in a blood culture vessel using a chemical sensor disposed in the sample container) that suggests using a laser spectroscopy technique for examining the culture vessels stored in Carr et al. The

Examiner has not cited anything in Sussman et al. or the other references that suggest using the measurement techniques described in those references (e.g. laser spectroscopy, FT-IR, etc.) for samples in an apparatus like the one described in Berndt et al. Nothing in Berndt et al. suggest an apparatus that might be configured to place a sample container in proximity to a laser source and detector for the system recited in claim 79. It is for these reasons applicants submit that claims 88 and 89 are patentable over the cited combination of references.

With regard to claim 91, the Examiner rejected this claim on the same basis used to reject claim 79. Applicants note that the Examiner did not cite any additional references in support of his obviousness rejection of claim 91 beyond those cited in support of the rejection of claim 79.

With regard to claim 91, none of the cited references disclose or suggest interrogating a sample using more than one laser. Note that all of the cited references describe the use of a single radiation source and a single detector. To the extent that multiple sources and multiple detectors might be contemplated, there is no teaching from the various cited references that two lasers might be used to interrogate for two different gases or two different samples (or both) in the same system. For this reason, applicants submit that claim 91 is clearly not obvious in view of the cited references. The applicants respectfully request the Examiner to withdraw the rejection of claim 91.

With regard to claim 92, applicants submit that this claim is patentable over the cited references for the same reason claim 79 is patentable over those references. Applicants respectfully request the Examiner to withdraw the rejection of claim 92.

With regard to claims 96-99, these claims have been amended to depend from claim 79. The Examiner previously

rejected these claims in view of the references applied to claim 79 taken further in view of Ahnell and further in view of "Allen" (Measurement Science and Technology).

The references applied to claim 79 were discussed in detail above and are not discussed in detail in the context of applicants' response to the Examiner's rejection of these claims. Specifically, claims 96-99 specify the substantially single wavelength of radiation for the detection of NH_3 gas, H_2S gas, CH_4 gas and CO_2 gas, respectively.

Applicants have previously stated why the references cited by the Examiner do not render obvious the claimed system for detecting the presence of a target gas in a container. The target gas is the byproduct of a metabolic process in the container. The claimed system uses a monomodal laser (a laser that emits at a substantially single wavelength) and the detector monitors the absorption spectrum of the radiation transmitted through the gas-containing portion of the container to determine a property (i.e. presence, pressure, concentration) of the target gas in the container. In the context of traversing the rejections of claims 79 and 65, applicants have explained why the cited combination of references does not render these claims (which recite, respectively, the emission wavelengths of 2.004 microns (for CO_2 detection) and 761.5 nm (for oxygen detection)). As previously noted, Ahnell proposes the detection of carbon dioxide, ammonia, oxygen, and other gases as evidence of biological activity in a sample, but describes the use of mass spectroscopy to detect the target gas. Ahnell does not disclose or suggest using a monomodal laser to detect a gas using absorption spectroscopy. Similarly, the Allen reference might suggest using lasers to detect the presence of certain gases in effluents. However, Allen, when combined with the other references, does not teach or suggest a monomodal laser source transmitting radiation at the wavelengths

specified in claims 96-99 in order to detect the presence of the claimed gases in those containers. It is for this reason applicants respectfully request the Examiner to withdraw the rejection of claims 96-99.

Applicants provide amended claims herewith. Specifically, claim 113 and the claims dependent thereon (claims 114-122) recite a system with a plurality of lasers. Each laser emits radiation at a substantially single wavelength at which a target gas selected from the group consisting of O₂, CO₂, NH₃, H₂S and CH₄ absorbs radiation. At least one of the lasers emits radiation at a wavelength that is different from the wavelength at which a second laser emits radiation. Support for this amendment is found at paragraph [0050].

Claims 123-145 recite a system having a plurality of laser/detector pairs, the lasers operating at a substantially single wavelength. At least one of the lasers emits radiation at a wavelength that is different from the wavelength at which a second laser emits radiation. Claim 123 and the claims dependent thereon further recite a detector assembly with a bracket that supports the laser/detector pairs in a spaced relation to permit a portion of the containers to pass therethrough. The claims further recite relative movement between the sample containers and the bracket so that the laser/detector pairs can be brought into proximity with the sample containers. Support for these claims is found in FIGs. 4-6 and 10-18 and the associated text.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's

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attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated:

Respectfully submitted,

By 

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